



DIVISION OF DISABILITY AND ELDER SERVICES

SOUTHERN REGIONAL OFFICE
BUREAU OF QUALITY ASSURANCE
2917 INTERNATIONAL LANE, SUITE 210
MADISON WI 53704

Jim Doyle
Governor

Helene Nelson
Secretary

State of Wisconsin
Department of Health and Family Services

Telephone: 608-243-2370
FAX: 608-243-2389
www.dhfs.state.wi.us

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BQA Memo 03-008

Supersedes memos 99-013 and 00-082

To:	Adult Family Homes	AFH – 02
	Adult Day Care	ADC – 01
	Ambulatory Surgery Centers	ASC – 02
	Certified Mental Health & AODA Treatment Programs	CMHA – 02
	Community Based Residential Facilities	CBRF – 02
	End Stage Renal Dialysis	ESRD – 02
	Facilities for the Developmentally Disabled	FDD – 03
	Home Health Agencies	HHa – 03
	Hospices	HSPC – 05
	Hospitals	HOSP – 05
	Laboratories	CLIA – 01
	Nursing Homes	NH – 05
	Outpatient Rehabilitation Agencies	OPRA – 01
	Residential Care Apartment Complexes	RCAC – 02
	Rural Health Clinics	RHC – 01

From: Jane Walters, Chief, Health Services Section

cc: Susan Schroeder, Director, Bureau of Quality Assurance

For All Facilities Performing Tests on Human Specimens: CLIA Requirements

Under the authority of Section 353 of the Public Health Service Act, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) require **all facilities performing tests on human specimens to be certified to perform these tests**. The regulations that implemented CLIA became effective September 1, 1992.

These regulations also apply to testing performed in facilities without conventional laboratories, such as care and service residential facilities, ambulances, health fairs, home health agencies, pharmacies, end stage renal dialysis facilities, etc.

Collection of blood or other specimens does **not** require CLIA certification. **Testing specimens is regulated and requires a CLIA certificate.**

If employees of a facility, or individuals contracted by the facility, perform testing on human specimens, the facility must have a CLIA certificate. There are four types of CLIA certificates: Certificate of Waiver, Certificate for Provider Performed Microscopy Procedures, Certificate of Compliance, and Certificate of Accreditation. Testing performed in residential health care settings is generally included in

the tests allowable under the Certificate of Waiver, e.g., whole blood glucose testing or occult blood testing (stool or gastric).

For questions, or to obtain an application for CLIA certification, please contact the Clinical Laboratory Unit, (608) 243-2023 or E-mail the Bureau of Quality Assurance via Plicclia@dhfs.state.wi.us. CLIA applications (form CMS 116) are also available via <http://cms.gov/forms/>. The federal CLIA site at <http://cms.hhs.gov/clia/> may also be useful.